

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

BARRY HOLTZMAN, derivatively on behalf of  
BRAINSTORM CELL THERAPEUTICS INC.,

Plaintiff,

v.

CHAIM LEOVITS, STACY LINDBORG,  
JUNE S. ALMENOFF, IRIT ARBEL,  
MENGHISTEAB BAIRU, JACOB FRENKEL,  
ANTHONY POLVERINO, MALCOLM TAUB,  
RALPH KERN, NIR NAOR, JEROLD CHUN,  
STANLEY H. APPEL, AMIT BAR-OR, and URI  
YABLONKA,

Defendants,

and

BRAINSTORM CELL THERAPEUTICS INC.,

Nominal Defendant.

Case No.: 1:24-cv-02139

**DEMAND FOR JURY TRIAL**

**VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT**

Plaintiff Barry Holtzman (“Plaintiff”), by Plaintiff’s undersigned attorneys, derivatively and on behalf of Nominal Defendant Brainstorm Cell Therapeutics Inc. (“Brainstorm Cell” or the “Company”), files this Verified Shareholder Derivative Complaint against defendants Chaim Lebovits (“Lebovits”), Stacy Lindborg (“Lindborg”), June S. Almenoff (“Almenoff”), Irit Arbel (“Arbel”), Menghisteab Bairu (“Bairu”), Jacob Frenkel (“Frenkel”), Anthony Poverino (“Poverino”), Malcolm Taub (“Taub”), Ralph Kern (“Kern”), Nir Naor (“Naor”), Jerold Chun (“Chun”), Stanley H. Appel (“Appel”), Amit Bar-Or (“Bar-Or”), and Uri Yablonka (“Yablonka”) (collectively, the “Individual Defendants” and with Brainstorm Cell, “Defendants”) for breaches

of their fiduciary duties as directors and/or officers of Brainstorm Cell, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), and against Defendants Lebovits and Lindborg for contribution under Sections 10(b) and 21D of the Exchange Act. As for Plaintiff’s complaint against the Individual Defendants, Plaintiff alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by the Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Brainstorm Cell, legal filings, news reports, securities analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Brainstorm Cell’s directors and officers from August 15, 2022 to September 27, 2023, inclusive (the “Relevant Period”).

2. Brainstorm Cell is a Delaware corporation based in New York that purportedly develops autologous cellular therapies for the treatment of neurodegenerative diseases, including Amyotrophic Lateral Sclerosis (“ALS”), Progressive Multiple Sclerosis, Alzheimer’s disease, and other neurodegenerative diseases. Brainstorm Cell developed NurOwn, a proprietary cell therapy platform that was purportedly designed for the treatment of ALS.

3. On August 15, 2022, before market hours, Brainstorm Cell issued a press release announcing its submission of a Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) for NurOwn for the treatment of ALS. According to the FDA’s website, the BLA is “a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce.”<sup>1</sup> The press release emphasized the effectiveness of NurOwn, representing, among other things, that “[n]ew clinical analyses strengthen the conclusions from NurOwn’s Phase 3 clinical trial[.]” However, the press release failed to reveal, among other things, that NurOwn’s effectiveness had been grossly overstated by the Defendants. Similar statements touting the effectiveness of NurOwn in the treatment of ALS were made by Defendants throughout the Relevant Period.

4. On October 12, 2022, after market hours, Brainstorm Cell issued a press release to announce the presentation of new biomarker analyses from its NurOwn Phase 3 ALS study.

5. The truth began to emerge on November 10, 2022 when the Company issued a press release entitled “BrainStorm Cell Therapeutics Receives Refusal to File Letter from FDA for its New Biologics License Application for NurOwn for the treatment of ALS.” In the press release, Defendants represented to investors that “*the FDA ha[d] not accepted [the Company’s] BLA for NurOwn in ALS*” but that Defendants “remain committed to NurOwn’s advancement as a treatment for this devastating disease.” (Emphasis added.) Defendants also noted that the

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<sup>1</sup> [https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber#:~:text=The%20Biologics%20License%20Application%20\(BLA,under%2021%20CFR%20600%20%E2%80%93%20680.](https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber#:~:text=The%20Biologics%20License%20Application%20(BLA,under%2021%20CFR%20600%20%E2%80%93%20680.)

Company intended “to request a Type A meeting and look[ed] forward to continued discussions with the FDA[.]”

6. On this news, the Company’s share price fell \$1.22 per share, or 42.21%, from a closing price of \$2.89 on November 9, 2022 to close at \$1.67 per share on November 10, 2022.

7. The truth fully emerged on September 27, 2023. That day, the Company announced in a press release the results of the FDA’s review of its BLA, revealing that members of the Cellular, Tissue, and Gene Therapies Advisory Committee voted 17 to 1 that there was not substantial evidence to show NurOwn’s effectiveness in treating ALS. The FDA briefing document further revealed that the Company had grossly downplayed the risks associated with NurOwn, stating that “*the submission was scientifically incomplete to demonstrate substantial evidence of effectiveness, and that the manufacturing information was grossly deficient to ensure adequate product quality.*” (Emphasis added.)

8. The same day, September 27, 2023, *Reuters* published an article entitled, “US FDA panel votes against BrainStorm's ALS therapy over effectiveness concern.” Lisa Lee, one of the panelists, stated, “providing false hope can be ethically problematic and false hope is provided when the probability of a positive outcome is overestimated. And I think that seems to be the case here.”

9. On this news, the Company’s share price fell \$0.19 per share, or 48.72%, from a closing price of \$0.39 per share on September 27, 2023 to close at \$0.20 per share on September 28, 2023.

10. During the Relevant Period, the Individual Defendants breached their fiduciary duties to the Company by personally making and/or causing the Company to make to the investing

public a series of materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements that failed to disclose, *inter alia*, that: (1) the Company downplayed the severity of the FDA's refusal to file letter; (2) the Company continued to conceal the risks associated with the submission of the BLA; and (3) as a result of the foregoing, Defendants' statements about Brainstorm Cell's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

11. The Individual Defendants also breached their fiduciary duties by failing to correct and/or causing the Company to fail to correct these false and misleading statements and omissions of material fact

12. Additionally, in breach of their fiduciary duties, the Individual Defendants caused the Company to fail to maintain adequate internal controls.

13. In light of the Individual Defendants' misconduct—which has subjected the Company, its Chief Executive Officer ("CEO"), and its Co-CEO to a federal securities fraud class action lawsuit pending in the United States District Court for the Southern District of New York (the "Securities Class Action") and which has further subjected the Company to the need to undertake internal investigations, the need to implement adequate internal controls, losses from the waste of corporate assets, and losses due to the unjust enrichment of the Individual Defendants who were improperly overcompensated by the Company and/or who benefitted from the wrongdoing alleged herein—the Company will have to expend many millions of dollars.

14. The Company has been substantially damaged as a result of the Individual Defendants' knowing or highly reckless breaches of fiduciary duty and other misconduct.

15. In light of the breaches of fiduciary duty engaged in by the Individual Defendants, most of whom are the Company's current directors, of the collective engagement in fraud and misconduct by the Company's directors, of the substantial likelihood of the directors' liability in this derivative action, of the CEO's and Co-CEO's liability in the Securities Class Action, and of their not being disinterested and/or independent directors, a majority of the Company's Board of Directors (the "Board") cannot consider a demand to commence litigation against themselves on behalf of the Company with the requisite level of disinterestedness and independence.

#### **JURISDICTION AND VENUE**

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act (15 U.S.C. § 78n(a)(1)), Rule 14a-9 of the Exchange Act (17 C.F.R. § 240.14a-9), Section 10(b) of the Exchange Act (15 U.S.C. § 78j(b)), and Section 21D of the Exchange Act (15 U.S.C. § 78u-4(f)). Plaintiff's claims also raise a federal question pertaining to the claims made in the Securities Class Action based on violations of the Exchange Act.

17. Additionally, diversity jurisdiction is conferred by 28 U.S.C. § 1332. Plaintiff and Defendants are citizens of different states, and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

18. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

19. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

20. Venue is proper in this District because the alleged misstatements and wrongs complained of herein entered this District, the Defendants have conducted business in this District, and Defendants' actions have had an effect in this District.

### **PARTIES**

#### **Plaintiff**

21. Plaintiff currently owns 1,035 shares of Company stock. Plaintiff has continuously owned Company stock since March 17, 2020, when he first purchased it. Plaintiff is a citizen of Nevada.

#### **Nominal Defendant Brainstorm Cell**

22. Brainstorm Cell is a Delaware corporation with its principal executive offices at 1325 Avenue of Americas, 28th Floor, New York, New York 10019. Brainstorm Cell's shares trade on the NASDAQ Stock Market ("NASDAQ") under the ticker symbol "BCLI."

#### **Defendant Lebovits**

23. Defendant Lebovits has served as the Company's CEO since September 2015 and as its President since July 2007. According to the proxy statement the Company filed with the SEC on November 8, 2023 (the "2023 Proxy Statement"), as of October 31, 2023, Defendant Lebovits beneficially owned 2,663,761 shares of the Company's common stock, representing 5.45% of the Company's total issued and outstanding common stock. Given that the price per share of the Company's common stock at the close of trading on October 31, 2023 was \$0.15, Defendant Lebovits owned approximately \$399,564 worth of Brainstorm Cell stock.

24. For the fiscal year ended December 31, 2022 (the “2022 Fiscal Year”), Defendant Lebovits received \$1,117,966 in total compensation from the Company. This included \$500,000 in salary, \$250,000 in bonus, \$127,547 in stock awards, and \$240,419 in all other compensation.

25. Upon information and belief, Defendant Lebovits is a citizen of New York.

26. The 2023 Proxy Statement stated the following about Defendant Lebovits:

Chaim Lebovits has served as our Chief Executive Officer since September of 2015, and has served as our President since January 2023. Mr. Lebovits joined the Company as President in connection with his arrangement of an equity investment by ACC BioTech in the Company in July 2007. On August 1, 2013, the Company appointed Mr. Lebovits as its Principal Executive Officer, and he assumed the duties and responsibilities of the Chief Executive Officer on an interim basis until June 2014. During his tenure with the Company, Mr. Lebovits has been instrumental in the various capital raises undertaken by the Company and in his capacity as President Mr. Lebovits managed relatively low burn rates and was very instrumental in the major decisions of the Company’s focus and direction, including the decision to focus on Amyotrophic Lateral Sclerosis (“ALS”, also known as Lou Gehrig’s Disease) as a first indication. Mr. Lebovits led efforts to attract the clinical sites first in Israel and later in the United States, building strong relationships for the Company with many leading Key Opinion Leaders and Centers of Excellence for ALS in the United States. Mr. Lebovits controls ACC Holdings International, and its subsidiaries including ACC BioTech, which is focused on the biotechnology sector. He has been at the forefront of natural resource management and has spent years leading the exploration and development of resources in Israel and served as a member of the boards of directors of several companies in the industry. Mr. Lebovits has also held senior positions for the worldwide Chabad Lubavitch organization, the largest Jewish organization in the world today.

**Defendant Lindborg**

27. Defendant Lindborg has served as the Company’s Co-CEO since January 2023. Prior to this, Defendant Lindborg served as the Company’s Executive Vice President and Chief Development Officer from June 2020 to January 2023. According to the 2023 Proxy Statement, as of October 31, 2023, Defendant Lindborg beneficially owned 281,500 shares of the Company’s common stock. Given that the price per share of the Company’s common stock at the close of



trading on October 31, 2023 was \$0.15, Defendant Lindborg owned approximately \$42,225 worth of Brainstorm Cell stock.

28. For the 2022 Fiscal Year, Defendant Lindborg received \$851,543 in total compensation from the Company. This included \$469,000 in salary, \$164,150 in bonus, \$143,150 in stock awards, and \$75,243 in all other compensation.

29. Upon information and belief, Defendant Lindborg is a citizen of Massachusetts.

30. The 2023 Proxy Statement stated the following about Defendant Lindborg:

Dr. Stacy Lindborg has served as our Co-Chief Executive Officer since January 2023. Prior to this, from June 2020 to January 2023, Dr. Lindborg served as our Executive Vice President and Chief Development Officer. She currently serves on the board of directors of Imunon, Inc. (formerly Celsion Corporation), a publicly-traded clinical stage biotechnology company. Dr. Lindborg previously served at Biogen Inc. (“Biogen”) from 2012 to 2020, where she was most recently Vice President, Analytics and Data Science. She also served on the R&D governance team during a time of significant growth for Biogen, and was active in guiding the firm’s long-term vision for growth through analytics and by stimulating innovative development platforms to increase productivity. Prior to her role at Biogen, Dr. Lindborg worked at Eli Lilly & Company, where she held positions of increasing responsibility. In her role as the Head of R&D strategy, she was responsible for characterizing the productivity of the portfolio and driving key R&D strategy projects including the annual R&D Long-Range Plan. Additionally, she was Leader of Zyprexa Product Management in which she was responsible for R&D, Commercial and Manufacturing plans. Dr. Lindborg holds a Ph.D. in statistics from Baylor University.

**Defendant Almenoff**

31. Defendant Almenoff has served as a Company director since February 26, 2017. Defendant Almenoff also served on the Audit Committee until December 2023. According to the 2023 Proxy Statement, as of October 31, 2023, Defendant Almenoff beneficially owned 13,175 shares of the Company’s common stock. Given that the price per share of the Company’s common

stock at the close of trading on October 31, 2023 was \$0.15, Defendant Almenoff owned approximately \$1,976 worth of Brainstorm Cell stock.

32. For the 2022 Fiscal Year, Defendant Almenoff received \$30,000 in total compensation from the Company, which consisted entirely of fees earned or paid in cash.

33. Upon information and belief, Defendant Almenoff is a citizen of North Carolina.

34. The proxy statement the Company filed with the SEC on December 13, 2022 (the “2022 Proxy Statement”) stated the following about Defendant Almenoff:

Dr. June S. Almenoff joined the Company on February 26, 2017 as a director. Dr. Almenoff currently serves as the Chief Medical Officer at RedHill Biopharma Inc. (Nasdaq: RDHL), where she focuses on medical-commercial strategy and serves on the commercial executive team. She is on the investment advisory board of the Harrington Discovery Institute, a private venture philanthropy, Board Director to Avalo Therapeutics (Nasdaq: ATVX) and Tenax (Nasdaq: TENX). She previously served as a Board Director to Tigenix (Nasdaq: TIG, acquired by Takeda), Ohr Pharmaceuticals (Nasdaq: OHRP, merged with Neubase Pharmaceutical), Kurome, RDD Pharma, Furiex Pharmaceuticals. Dr. Almenoff previously served as Chief Medical Officer (CMO) and Chief Operating Officer of Innovate Biopharmaceuticals in 2018 and as President and CMO of Furiex Pharmaceuticals (acquired by Actavis plc) from 2010 to 2014. Prior to joining Furiex, Dr. Almenoff was at GlaxoSmithKline for 12 years, where she was a Vice President in the Clinical Safety organization, chaired a PhRMA-FDA working group, and worked in scientific licensing. Dr. Almenoff has also served as an advisor to numerous biopharma and venture capital organizations, and as a consultant to biopharma hedge funds. Dr. Almenoff received her B.A. from Smith College and graduated from the M.D.-Ph.D. program at the Icahn (Mt. Sinai) School of Medicine. She completed post-graduate medical training at Stanford University Medical Center and served on the faculty of Duke University School of Medicine. She is an adjunct Professor at Duke and a Fellow of the American College of Physicians (FACP). We believe Dr. Almenoff possesses specific attributes that qualify her to serve on our Board including her valuable leadership skills and her deep knowledge of pharmaceutical product development.

**Defendant Arbel**

35. Defendant Arbel co-founded the Company and has served as a Company director since May 2004. She also serves as the Vice-Chairperson of the Board, as the Chair of the Governance, Nominating and Compensation Committee, and as a member of the Audit Committee. According to the 2023 Proxy Statement, as of October 31, 2023, Defendant Arbel beneficially owned 383,831 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on October 31, 2023 was \$0.15, Defendant Arbel owned approximately \$57,575 worth of Brainstorm Cell stock.

36. Upon information and belief, Defendant Arbel is a citizen of Israel.

37. The 2023 Proxy Statement stated the following about Defendant Arbel:

Dr. Irit Arbel, one of the Company's co-founders, joined the Company in May 2004 as a director and served as President of the Company for six months. Currently, Dr. Arbel is the Vice-Chairperson of the Board and the Chair of the Governance, Nominating and Compensation Committee. She previously served as Chief Executive Officer of Neurochords Corp ("Neurochords"), a biotechnology firm developing graphene-based scaffolds for nerve reconstruction in the acute spinal cord and peripheral nerve injury, from August 2018 to 2020. Prior to Neurochords, Dr. Arbel served as Executive Vice President, Research and Development at Savicell Diagnostic Ltd from July 2012 until August 2018. From 2009 through 2011, Dr. Arbel served as Chairperson of Real Aesthetics Ltd., a company specializing in cellulite ultrasound treatment, and BRH Medical, a developer of medical devices for wound healing. She was also Director of M&A at RFB Investment House, a private investment firm focusing on early stage technology related companies. Previously, Dr. Arbel was President and Chief Executive Officer of Pluristem Life Systems, Inc., a biotechnology company, and prior to that, Israeli Sales Manager of Merck, Sharp & Dohme, a pharmaceutical company. Dr. Arbel earned her Post Doctorate degree in 1997 in Neurobiology, after performing research in the area of Multiple Sclerosis. Dr. Arbel also holds a Chemical Engineering degree from the Technion, Israel's Institute of Technology. We believe Dr. Arbel possesses specific attributes that qualify her to serve on our Board, including Dr. Arbel's extensive experience in the biotechnology field and significant leadership skills as a chief executive officer. Dr. Arbel previously served as our President, which has given her a deep knowledge of the Company and its business and directly relevant management experience.

**Defendant Bairu**

38. Defendant Bairu has served as a Company director since October 2021. He has also served as a member of the Audit Committee since December 18, 2023.

39. According to the 2023 Proxy Statement, pursuant to an October 28, 2021 resolution of the Board, Defendant Bairu receives an annual cash award in the amount of \$30,000, paid in biannual installments, from the Company as compensation for his service on the Board.

40. Upon information and belief, Defendant Bairu is a citizen of California.

41. The 2023 Proxy Statement stated the following about Defendant Bairu:

Dr. Menghisteab Bairu joined the Company in October 2021 as a director. Since December 2016, Dr. Bairu has served as the founder, chairman and Chief Executive Officer of Proxenia Venture Partners, which focuses on companies in late preclinical and early-stage clinical development in biotechnology. Dr. Bairu has also served as Chairman and Chief Executive Officer of Bairex, an international medical education and market research organization focused on Africa and the Middle East since December 2018. Dr. Bairu also served as Executive Chairman of Treos Bio Limited from 2016 to 2019, a start-up company that uses computational biology to develop precision cancer immunotherapies tailored to patients' genetics. In addition, he is Founder and Chairman Emeritus of Serenus Biotherapeutics, Inc., an emerging market focused specialty biopharmaceutical company, and has served on its board since 2013. Dr. Bairu received his M.D. from Università degli Studi di Milano and currently serves as Adjunct Professor at the University of California, San Francisco School of Medicine, where he lectures on global clinical trials' design, development, and conduct. We believe that Dr. Bairu possesses specific attributes that qualify him to serve on our Board, including his valuable leadership skills and his deep knowledge of pharmaceutical product development.

**Defendant Frenkel**

42. Defendant Frenkel has served as a Company director and Chairperson since March 2020. According to the 2023 Proxy Statement, as of October 31, 2023, Defendant Frenkel beneficially owned 206,667 shares of the Company's common stock. Given that the price per share

of the Company's common stock at the close of trading on October 31, 2023 was \$0.15, Defendant Frenkel owned approximately \$31,000 worth of Brainstorm Cell stock.

43. For the 2022 Fiscal Year, Defendant Frenkel received \$152,811 in total compensation from the Company, which consisted entirely of options awards.

44. Upon information and belief, Defendant Frenkel is a citizen of New York.

45. The 2023 Proxy Statement stated the following about Defendant Frenkel:

Dr. Jacob Frenkel joined the Company in March 2020 as a director and Chairperson. Dr. Frenkel serves as Chairman of the Board of Trustees of the Group of Thirty, which is a private, nonprofit, Consultative Group on International Economic and Monetary Affairs. Dr. Frenkel served as Chairman of JPMorgan Chase International from 2009 to 2020 and is currently serving as a Senior Advisor to JPMorgan Chase. From 2001 to 2011 he served as Chairman and Chief Executive Officer of the G-30, from 2004 to 2009 as Vice Chairman of American International Group, Inc., and from 2000 to 2004 as Chairman of Merrill Lynch International. Between 1991 and 2000 he served two terms as the Governor of the Bank of Israel. Dr. Frenkel serves as Chairman of the Board of Governors of Tel Aviv University, where he is also Chairman of the Frenkel-Zuckerman Institute for Global Economics. He holds a B.A. in economics and political science from the Hebrew University of Jerusalem, and an M.A. and Ph.D. in economics from the University of Chicago. We believe Dr. Frenkel possesses specific attributes that qualify him to serve on our Board, including his valuable leadership skills and his deep knowledge of the financial industry.

**Defendant Polverino**

46. Defendant Polverino has served as Company director since February 2018. He also serves as a member of the Governance, Nominating and Compensation Committee. According to the 2023 Proxy Statement, as of October 31, 2023, Defendant Polverino beneficially owned 25,960 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on October 31, 2023 was \$0.15, Defendant Polverino owned approximately \$3,894 worth of Brainstorm Cell stock.

47. For the 2022 Fiscal Year, Defendant Polverino received \$24,612 in total compensation from the Company. This included \$12,500 in fees earned or paid in cash and \$12,112 in stock awards.

48. Upon information and belief, Defendant Polverino is a citizen of Washington.

49. The 2023 Proxy Statement said the following about Defendant Polverino:

Dr. Anthony Polverino joined the Company on February 5, 2018 as a director. Dr. Polverino is currently an independent consultant to corporate executives and board members. Dr. Polverino was an Executive Vice President Early Development and Chief Scientific Officer of Zymeworks Inc. (“Zymeworks”) from September of 2018 to January 2022, and where he was responsible for establishing the vision, strategy, and general management of the organization and overseeing the advancement of products from discovery research through translational research/early development to create a seamless link to clinical development. Prior to Zymeworks, Dr. Polverino was the interim Chief Scientific Officer of Kite Pharma, Inc. (“Kite”) (now a wholly-owned subsidiary of Gilead Sciences), which he joined in 2015, and where he was responsible for establishing Kite’s strategic non-clinical R&D roadmap to support its current and future portfolio. Prior to this, he was the Vice President of research at Kite, where his responsibilities included corporate goal setting, budget allocation, scientific and investor interactions, business development in-licensing and partnership deals. Dr. Polverino spent 20 years in positions of increasing responsibilities at Amgen, Inc. (“Amgen”), most recently as executive director of its Therapeutic Innovation Unit, where he managed research programs in oncology, metabolic disease, inflammatory disease and schizophrenia. Prior to Amgen, he was a postdoctoral scientist at Cold Spring Harbor Laboratory, where he worked primarily on oncology research. He earned a B.Sc. in Biochemistry/Physiology and a B.Sc. (Honors) in Pharmacology, both from Adelaide University in Adelaide, Australia and a Ph.D. in Biochemistry from Flinders University, also in Adelaide. We believe that Dr. Polverino possesses specific attributes that qualify him to serve on our Board, including his deep knowledge of the pharmaceutical industry.

**Defendant Taub**

50. Defendant Taub served as a Company director from March 2009 until he resigned on June 15, 2023. Prior to his resignation, Defendant Taub served as Chairman of the Audit Committee.

51. Upon information and belief, Defendant Taub is a citizen of New York.

52. The 2022 Proxy Statement said the following about Defendant Taub:

Malcolm Taub joined the Company in March 2009 as a director. Mr. Taub currently serves as the Managing Partner of Taub & Lewis LLP, a full-service law firm in New York. From October 2010 to December 2019, Mr. Taub has been a Partner at Davidoff Malito & Hutcher LLP, a full-service law and government relations firm. From 2001 to September 30, 2010, Mr. Taub was the Managing Member of Malcolm S. Taub LLP, a law firm which practiced in the areas of commercial litigation, among other practice areas. Mr. Taub also works on art transactions, in the capacity as an attorney and a consultant. Mr. Taub has also served as a principal of a firm which provides consulting services to private companies going public in the United States. Mr. Taub has acted as a consultant to the New York Stock Exchange in its Market Surveillance Department. Mr. Taub acts as a Trustee of The Gateway Schools of New York and The Devereux Glenholme School in Washington, Connecticut. Mr. Taub has served as an adjunct professor at Long Island University, Manhattan Marymount College and New York University Real Estate Institute. Mr. Taub holds a B.A. from Brooklyn College and a J.D. from Brooklyn Law School. Mr. Taub formerly served on the Board of Directors of Safer Shot, Inc. (formerly known as Monumental Marketing Inc.). We believe that Mr. Taub possesses specific attributes that qualify him to serve on our Board including Mr. Taub's vast law experience and his demonstrated leadership skills as a managing member of a law firm.

**Defendant Yablonka**

53. Defendant Yablonka has served as a Company director since June 2014 and as the Company's Executive Vice President, Chief Business Officer since March 6, 2017. He also previously served as the Company's Chief Operating Officer from June 2014 until March 6, 2017. According to the 2023 Proxy Statement, as of October 31, 2023, Defendant Yablonka beneficially owned 157,540 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on October 31, 2023 was \$0.15, Defendant Yablonka owned approximately \$23,631 worth of Brainstorm Cell stock.

54. Upon information and belief, Defendant Yablonka is a citizen of New Jersey.



55. The 2023 Proxy Statement stated the following about Defendant Yablonka:

Uri Yablonka joined the Company on June 6, 2014 as Chief Operating Officer and as a director. On March 6, 2017 he was appointed Executive Vice President, Chief Business Officer and ceased to serve as the Company's Chief Operating Officer. Prior to joining the Company, beginning in 2010, Mr. Yablonka served as owner and General Manager of Uri Yablonka Ltd., a business consulting firm. From January 2011 to May 2014, he served as Vice President, Business Development at ACC International, an affiliate of ACCBT. Prior to his role in ACC International, Mr. Yablonka served as Senior Partner of PM-PR Media Consulting Ltd. from 2008 to January 2011, where he led public relations and strategy consulting for a wide range of governmental and private organizations. From 2002 to 2008, he served as a correspondent at the Maariv Daily News Paper, including extensive service as a Diplomatic Correspondent. Mr. Yablonka holds an LL.B from Ono Academic College and an LL.M from Bar-Ilan University, and is a member of the Israeli Bar Association. We believe that Mr. Yablonka's skills and experience provide the variety and depth of knowledge, judgment and vision necessary for the effective oversight of the Company. His experience in business consulting and development and media experience are expected to be valuable to the Company in its current stage of growth and beyond, and his governmental experience can provide valuable insight into issues faced by companies in regulated industries such as ours. We believe that these skills and experiences qualify Mr. Yablonka to serve as a director and secretary of the Company.

**Defendant Kern**

56. Defendant Kern has served on the Company's Scientific Advisory Board since January 20, 2023. Prior to this, he served as the Company's President and Chief Medical Officer from March 2017 until his retirement from both positions on January 3, 2024. The 2023 Proxy Statement states that the Scientific Advisory Board "advises the management team on scientific matters such as research, clinical trials and drug development."

57. For the 2022 Fiscal Year, Defendant Kern received \$812,559 in total compensation from the Company. This included \$500,000 in salary, \$150,000 in bonus, \$106,220 in stock awards, and \$56,339 in all other compensation.

58. Upon information and belief, Defendant Kern is a citizen of New York.

59. The Company's website states the following about Defendant Kern:



Ralph Kern, MD, MHSc, was the President and Chief Medical Officer at BrainStorm from March 2017-January 2023. He brought significant industry and neurodegenerative disease experience to the organization. His biotech experience includes senior medical roles at Genzyme, Novartis, and Biogen. At Novartis he was Vice President and Head of the Neuroscience Medical Team, leading the global launch of Gilenya® in relapsing remitting multiple sclerosis (rrMS). At Biogen he was Senior Vice President and Head of the Worldwide Medical Organization. His team launched Zinbryta® in rrMS and Spinraza® in spinal muscular atrophy (SMA), and developed the medical and scientific strategy for MS, SMA, and Alzheimer's disease.

Dr. Kern completed his neurology training at McGill University, practiced neuromuscular neurology at Mount Sinai Hospital in Toronto, and was head of the Postgraduate Academic Neurology Program at the University of Toronto. He completed further postgraduate training in Health Administration at the Institute for Health Policy Management and Evaluation at the University of Toronto. Dr. Kern received his MD degree from Queen's University, is board-certified in neurology and neuromuscular disease, and is a member of the Royal College of Physicians and Surgeons of Canada.

**Defendant Naor**

60. Defendant has served as a Company director since June 2023. He also serves as Chair of the Audit Committee and as a member of the Governance, Nominating and Compensation Committee.

61. Upon information and belief, Defendant Naor is a citizen of Georgia.

62. The 2023 Proxy Statement stated the following about Defendant Naor:

**Nir Naor** joined the Company in June 2023 as a director and as Chair of the Audit Committee. Mr. Naor has been serving in a finance advisory capacity to a number of private companies. Mr. Naor served as Chief Financial Officer of QuVa Pharma from February 2023 to September 2023. Mr. Naor previously served as the Chief Financial Officer of HMNC Brain Health from December 2021 to October 2022 and as the Chief Financial Officer of Arbor Pharmaceuticals from January 2021 to September 2021. Prior to this, Mr. Naor served as the Chief Financial Officer, U.S. and the Americas, of Molnlycke, from October 2017 to January 2021. Prior to this, Mr. Naor served as Chief Financial Officer, U.S., of UCB from July 2016 to July 2017. Previously, Mr. Naor held various senior leadership finance roles in the biopharmaceutical industry. Previously, Mr. Naor worked as an investment banker and as a commercial lawyer in Israel. Mr. Naor is a Certified Public Accountant (Israel, inactive) and a Chartered Financial Analyst, and holds an MBA from IMD Business School in Switzerland and

an MBA from Tel Aviv University in Israel, an L.L.M. from Hamburg University in Germany, and an L.L.B. in Law and a Bachelor degree in Accounting from Tel Aviv University in Israel. We believe that Mr. Naor possesses specific attributes that qualify him to serve on our Board, including his substantial experience in corporate finance and the biopharmaceutical industry.

**Defendant Chun**

63. Defendant Chun serves as a member of the Company's Scientific Advisory Board and has served in this role since the committee's formation in March 2018.

64. Upon information and belief, Defendant Chun is a citizen of California.

65. The Company's website states the following about Defendant Chun:

Dr. Jerold Chun is currently Professor and Senior Vice President of Neuroscience Drug Discovery at Sanford Burnham Prebys Medical Discovery Institute, with over 27 years of experience in academia and industry. He currently leads a team of 25 researchers in the study of genomic mosaicism (DNA sequence variation in brain cells) and lysophospholipid receptor signaling to understand and develop drug treatments for brain diseases such as Alzheimer's disease, multiple sclerosis, and hydrocephalus. Dr. Chun previously held professorships at The Scripps Research Institute, the University of California San Diego School of Medicine, and also headed the Department of Molecular Neuroscience at Merck Research Laboratories. Among his achievements, he identified the first lysophospholipid receptor (1996), was first to demonstrate genomic mosaicism in the brain (2001) and its alteration in Alzheimer's disease (2015). Dr. Chun is a recipient of over a dozen awards, has published ~300 scientific articles, and hold three patents. He received MD and PhD (Neuroscience) degrees through the Medical Scientist Training Program at Stanford University School of Medicine and was a Helen Hay Whitney Fellow at the Whitehead Institute for Biomedical Research/MIT.

**Defendant Appel**

66. Defendant Appel serves as a member of the Company's Scientific Advisory Board and has served in this role since March 2018.

67. Upon information and belief, Defendant Appel is a citizen of Texas.

68. The Company's website states the following about Defendant Appel:

Stanley H. Appel, MD, is the Peggy and Gary Edwards Distinguished Endowed Professor for the Treatment and Research of ALS, Department of Neurology, Neurological Institute, Houston Methodist Hospital and Professor of Neurology at Weill Medical College at Cornell University. He is Director of the MDA/ALS Research and Clinical Center at the Methodist Neurological Institute, and a past Director of The National Institute of Aging Alzheimer's Disease Research Center. He has received numerous awards for his accomplishments in neurology and biochemistry, including the Gold Medal Award in 1997 from Columbia College of Physicians and Surgeons for "Distinguished Achievements in Medicine" and the Sheila Essey Award in 2003 from the American Academy of Neurology for "outstanding research in Amyotrophic Lateral Sclerosis."

### **Defendant Bar-Or**

69. Defendant Bar-Or serves as a member of the Company's Scientific Advisory Board and has served in this role since March 2018.

70. Upon information and belief, Defendant Bar-Or is a citizen of Canada.

71. The Company's website states the following about Defendant Bar-Or:

Amit Bar-Or, MD, a neurologist and neuroimmunologist, is the Presidential Endowed Chair at the University of Pennsylvania (UPenn/CHOP). He is also the Melissa and Paul Anderson Professor of Neurology, Founder and Director of the Centre for Neuroinflammation and Experimental Neurotherapeutics, and Chief of the Multiple Sclerosis Division. He leads a cellular and molecular neuroimmunology lab that studies basic principles of immune regulation and immune-neural interaction, in the context of inflammation, injury, and repair of the human central nervous system (CNS). He is President-Elect of the International Society of Neuroimmunology (ISNI) and serves on the board of directors of the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS), and on the steering committee of the Immune Tolerance Network (ITN).

### **FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS**

72. By reason of their positions as officers, directors, and/or fiduciaries of Brainstorm Cell and because of their ability to control the business and corporate affairs of Brainstorm Cell, the Individual Defendants owed Brainstorm Cell and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control

and manage Brainstorm Cell in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Brainstorm Cell and its shareholders so as to benefit all shareholders equally.

73. Each director and officer of the Company owes to Brainstorm Cell and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligations of fair dealing.

74. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Brainstorm Cell, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

75. To discharge their duties, the officers and directors of Brainstorm Cell were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

76. Each Individual Defendant, by virtue of their position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Brainstorm Cell, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also the officers and directors of the Company

has been ratified by the remaining Individual Defendants who collectively comprised a majority of Brainstorm Cell's Board at all relevant times.

77. As the senior executive officers and/or directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, including the dissemination of false information regarding the Company's business, prospects, and operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful and accurate information. Further, they had a duty to ensure the Company remained in compliance with all applicable laws.

78. To discharge their duties, the officers and directors of Brainstorm Cell were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Brainstorm Cell were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware, New York, and the United States, and pursuant to Brainstorm Cell's own Code of Business Conduct and Ethics (the "Code of Ethics");

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) remain informed as to how Brainstorm Cell conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Brainstorm Cell and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Brainstorm Cell's operations would comply with all applicable laws and Brainstorm Cell's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(f) exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate

disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

79. Each of the Individual Defendants further owed to Brainstorm Cell and the shareholders the duty of loyalty requiring that each favor Brainstorm Cell's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

80. At all times relevant hereto, the Individual Defendants were the agents of each other and of Brainstorm Cell and were at all times acting within the course and scope of such agency.

81. Because of their advisory, executive, managerial, directorial, and controlling positions with Brainstorm Cell, each of the Individual Defendants had access to adverse, nonpublic information about the Company.

82. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Brainstorm Cell.

**CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION**

83. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

84. The purpose and effect of the conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (i) facilitate and disguise the Individual Defendants'

violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, gross mismanagement, abuse of control, and violations of the Exchange Act ; (ii) conceal adverse information concerning the Company's operations, financial condition, legal compliance, future business prospects, and internal controls; and (iii) artificially inflate the Company's stock price.

85. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company purposefully or recklessly to conceal material facts, fail to correct such misrepresentations, and violate applicable laws. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants who is a director of Brainstorm Cell was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

86. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in, or substantially assisted in the accomplishment of that wrongdoing, and was or should have been aware of his overall contribution to and furtherance of the wrongdoing.

87. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Brainstorm Cell and was at all times acting within the course and scope of such agency.



### **CODE OF ETHICS**

88. The Company's Code of Ethics represents that it "sets forth legal and ethical standards of conduct for employees, officers and directors of Brainstorm Cell Therapeutics Inc. and its subsidiaries (the 'Company'), including the Company's principal executive officer and its senior financial officers[.]"

89. The Code of Ethics provides, as to "Compliance with Laws, Rules and Regulations," that:

The Company requires that all employees, officers and directors comply with all laws, rules and regulations applicable to the Company wherever it does business. You are expected to use good judgment and common sense in seeking to comply with all applicable laws, rules and regulations and to ask for advice when you are uncertain about them.

If you become aware of the violation of any law, rule or regulation by the Company, whether by its employees, officers or directors, it is your responsibility to promptly report the matter to your supervisor or Legal Counsel. While it is the Company's desire to address matters internally, nothing in this Code should discourage you from reporting any illegal activity, including any violation of the securities laws, antitrust laws, environmental laws or any other federal, state or foreign law, rule or regulation, to the appropriate regulatory authority. Employees, officers and directors shall not discharge, demote, suspend, threaten, harass or in any other manner discriminate against an employee because he or she in good faith reports any such violation. This Code should not be construed to prohibit you from testifying, participating or otherwise assisting in any state or federal administrative, judicial or legislative proceeding or investigation.

90. The Code of Ethics provides, as to "Conflicts of Interest," the following, in relevant part:

Employees, officers and directors must act in the best interests of the Company. You must refrain from engaging in any activity or having a personal interest that presents a "conflict of interest." A conflict of interest occurs when your personal interest interferes with the interests of the Company. A conflict of interest can arise whenever you, as an employee, officer or director, take action or have an interest that prevents you from performing your Company duties and responsibilities honestly, objectively and effectively.

91. The Code of Ethics provides, as to “Honest and Ethical Conduct and Fair Dealing,”

that:

Keeping the best interests of the Company in mind, employees, officers and directors should endeavor to deal honestly, ethically and fairly with the Company’s suppliers, customers, competitors and employees. Statements regarding the Company’s products and services must not be untrue, misleading, deceptive or fraudulent. You must not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair-dealing practice.

92. The Code of Ethics provides, as to “Protection and Proper Use of Corporate

Assets,” that:

Employees, officers and directors should seek to protect the Company’s assets. Theft, carelessness and waste have a direct impact on the Company’s financial performance. Employees, officers and directors must use the Company’s assets and services solely for legitimate business purposes of the Company and not for any personal benefit or the personal benefit of anyone else.

Employees, officers and directors must advance the Company’s legitimate interests when the opportunity to do so arises. You must not take for yourself opportunities that are discovered through your position with the Company or the use of property or information of the Company.

93. The Code of Ethics provides, as to “Accuracy of Books and Public Reports,” that:

Employees, officers and directors must honestly and accurately report all business transactions. You are responsible for the accuracy of your records and reports. Accurate information is essential to the Company’s ability to meet legal and regulatory obligations.

All Company books, records and accounts shall be maintained in accordance with all applicable regulations and standards and accurately reflect the true nature of the transactions they record. The financial statements of the Company shall conform to generally accepted accounting principles and the Company’s accounting policies. No undisclosed or unrecorded account or fund shall be established for any purpose. No false or misleading entries shall be made in the Company’s books or records for any reason, and no disbursement of corporate funds or other corporate property shall be made without adequate supporting documentation (other than de minimis amounts).

It is the policy of the Company to provide full, fair, accurate, timely and understandable disclosure in reports and documents filed with, or submitted to, the Securities and Exchange Commission and in other public communications.

94. The Code of Ethics provides, as to “Concerns Regarding Accounting or Auditing Matters,” that:

Employees with concerns regarding questionable accounting or auditing matters or complaints regarding accounting, internal accounting controls or auditing matters may confidentially, and anonymously if they wish, submit such concerns or complaints in writing to Legal Counsel. See “Reporting and Compliance Procedures.” All such concerns and complaints of a material nature will be forwarded to the Audit Committee of the Board of Directors. In any event, a complete record of all complaints will be provided to the Audit Committee each fiscal quarter. Any such concerns or complaints may also be communicated confidentially and, if you desire, anonymously, directly to any member of the Audit Committee of the Board of Directors.

The Audit Committee will evaluate the merits of any concerns or complaints received by it and authorize such follow-up actions, if any, as it deems necessary or appropriate to address the substance of the concern or complaint.

The Company will not discipline, discriminate against or retaliate against any employee who reports a complaint or concern (unless the employee is found to have knowingly and willfully made a false report).

95. Regarding “Waivers of this Code of Business Conduct and Ethics,” the Code of Ethics states the following:

While some of the policies contained in this Code must be strictly adhered to and no exceptions can be allowed, in other cases exceptions may be possible. Any employee or officer who believes that an exception to any of these policies is appropriate in his or her case should first contact his or her immediate supervisor. If the supervisor agrees that an exception is appropriate, the approval of Legal Counsel must be obtained. Legal Counsel shall be responsible for maintaining a complete record of all requests for exceptions to any of these policies and the disposition of such requests.

Any executive officer, senior financial officer or director who seeks an exception to any of these policies should contact Legal Counsel. Any waiver of this Code for executive officers, senior financial officers or directors or any change to this Code that applies to executive officers, senior financial officers or directors may be made

only by the Board of Directors of the Company and will be disclosed as required by law or stock market regulation.

96. The Code of Ethics provides, as to “Reporting and Compliance Procedures,” the following, in relevant part:

Every employee, officer and director has the responsibility to ask questions, seek guidance, report suspected violations and express concerns regarding compliance with this Code. Any employee, officer or director who knows or believes that any other employee or representative of the Company has engaged or is engaging in Company-related conduct that violates applicable law or this Code should report such information to his or her supervisor or to Legal Counsel, as described below. You may report such conduct openly or anonymously without fear of retaliation. The Company will not discipline, discriminate against or retaliate against any employee who reports such conduct in good faith, whether or not such information is ultimately proven to be correct, or who cooperates in any investigation or inquiry regarding such conduct. Any supervisor who receives a report of a violation of this Code must immediately inform Legal Counsel.

You may report violations of this Code, on a confidential or anonymous basis, by contacting Legal Counsel by fax (617-399-6930), mail (Tom Rosedale, BRL Law Group LLC, 31 St. James Ave., Suite 850, Boston, MA 02116) or e-mail (trosedale@brllawgroup.com). While we prefer that you identify yourself when reporting violations so that we may follow up with you, as necessary, for additional information, you may remain anonymous if you wish.

97. In violation of the Code of Ethics, the Individual Defendants (as key officers and as members of the Company’s Board) conducted little, if any, oversight of the Company’s internal controls over public reporting of the Individual Defendants’ scheme to issue materially false and misleading statements to the public and their scheme to facilitate and disguise the Individual Defendants’ violations of law, including, but not limited to, breaches of fiduciary duty, gross mismanagement, and unjust enrichment. In violation of the Code of Ethics, the Individual Defendants consciously disregarded their duties to comply with the applicable laws and regulations, engage in fair dealing, avoid using corporate opportunities for personal gain, avoid

conflicts of interest, appropriately maintain the Company's books, records, accounts, and financial statements, and make accurate filings with the SEC.

**BRAINSTORM CELL'S AUDIT COMMITTEE CHARTER**

98. The Company also maintains an Audit Committee Charter. The purpose of the Audit Committee is "to assist the Board of Directors' oversight of the Company's accounting and financial reporting processes and the audits of the Company's financial statements." Regarding "Audited Financial Statements," the Audit Committee Charter states the following:

6. Review and Discussion. The Audit Committee shall review and discuss with the Company's management and independent auditor the Company's audited financial statements, including the matters about which Statement on Auditing Standards No. 61 (Codification of Statements on Auditing Standards, AU §380) requires discussion.

7. Recommendation to Board Regarding Financial Statements. The Audit Committee shall consider whether it will recommend to the Board of Directors that the Company's audited financial statements be included in the Company's Annual Report on Form 10-K.

8. Audit Committee Report. The Audit Committee shall prepare an annual committee report for inclusion where necessary in the proxy statement of the Company relating to its annual meeting of security holders.

99. Regarding "Controls and Procedures," the Audit Committee Charter stated the following:

10. Oversight. The Audit Committee shall coordinate the Board of Directors' oversight of the Company's internal control over financial reporting, disclosure controls and procedures and code of conduct. The Audit Committee shall receive and review the reports of the CEO and CFO required by Rule 13a-14 of the Exchange Act.

11. Procedures for Complaints. The Audit Committee shall establish procedures for (i) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters; and (ii) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.

12. Related-Party Transactions. The Audit Committee shall review all related party transactions on an ongoing basis, and all such transactions must be approved by the Audit Committee.

13. Additional Powers. The Audit Committee shall have such other duties as may be delegated from time to time by the Board of Directors.

100. Under a section titled “General,” the Audit Committee Charter states the following:

The Audit Committee shall discharge its responsibilities, and shall assess the information provided by the Company's management and the independent auditor, in accordance with its business judgment. Management is responsible for the preparation, presentation, and integrity of the Company's financial statements and for the appropriateness of the accounting principles and reporting policies that are used by the Company. The independent auditors are responsible for auditing the Company's financial statements and for reviewing the Company's unaudited interim financial statements. The authority and responsibilities set forth in this Charter do not reflect or create any duty or obligation of the Audit Committee to plan or conduct any audit, to determine or certify that the Company's financial statements are complete, accurate, fairly presented, or in accordance with generally accepted accounting principles or applicable law, or to guarantee the independent auditor's report.

101. In violation of the Audit Committee Charter, Defendants Almenoff and Arbel failed to adequately review and discuss the Company's quarterly earnings press releases; failed to adequately exercise their risk management and risk assessment functions; and failed to ensure adequate Board oversight of the Company's internal control over financial reporting, disclosure controls and procedures, and Code of Ethics.

### **THE INDIVIDUAL DEFENDANTS' MISCONDUCT**

#### **Background**

102. Brainstorm Cell is a Delaware corporation based in New York that purportedly develops autologous cellular therapies for the treatment of neurodegenerative diseases, including

ALS, Progressive Multiple Sclerosis, Alzheimer's disease, and other neurodegenerative diseases. Brainstorm Cell developed NurOwn, a proprietary cell therapy platform that was purportedly designed for the treatment of ALS.

### **False and Misleading Statements**

#### ***August 15, 2022 Press Release***

103. On August 15, 2022, before the market opened, Brainstorm Cell issued a press release announcing its decision to submit a BLA to the FDA for NurOwn for the treatment of ALS. The press release highlighted the effectiveness of NurOwn, representing the following, in relevant part:

#### **BrainStorm announces decision to submit a BLA to the FDA for NurOwn® for the treatment of ALS**

“Brainstorm Cell Therapeutics is at a pivotal moment as a company as we finalize the regulatory filing for NurOwn® in the treatment of ALS. The continued analysis and the feedback received from the many scientific presentations of NurOwn's® Phase 3 data have uncovered key insights that furthered our understanding of the product mechanism of action and therapeutic potential and strengthened the conclusions of NurOwn's® efficacy,” said Chaim Lebovits, Chief Executive Officer. *“After carefully considering these learnings, the totality of the evidence from NurOwn's® clinical studies, and the feedback received from key opinion leaders and the broader ALS community, we will submit a Biologics License Application to the FDA.* We are deeply grateful to the ALS clinical experts, members of the ALS community and faithful investors for their contribution to the development of NurOwn® and what it may mean to those living with ALS. Their contributions and commitment made our current progress possible and continue to inspire us as we prepare for the considerable work ahead. We intend to provide additional updates upon learning whether the FDA files our BLA submission.”

#### **New clinical analyses strengthen the conclusions from NurOwn's® Phase 3 clinical trial.**

A correction was made to the Muscle and Nerve publication from December 2021 describing the results of NurOwn's® Phase 3 clinical trial in ALS following new clinical analyses which strengthen the Company's original conclusions from the

trial. The correction results in a statistically significant treatment difference ( $p=0.050$ ) of more than 2 points for an important secondary endpoint, average change from baseline in ALSFRS-R, in the pre-specified efficacy subgroup of participants with a baseline score of at least 35. Analyses reported in the original publication utilized an efficacy model that unintentionally deviated from the trial's pre-specified statistical analysis plan by erroneously incorporating interaction terms between the subgroup and treatment. The newly published results, which includes supporting information to the publication, employ the efficacy model as pre-specified in the trial's statistical analysis plan, correcting the analyses. The correction also relates to the other subgroup analyses published for this endpoint, demonstrating that all subgroups with ALSFRS-R baseline scores of at least 26 to 35 showed a statistically significant benefit following treatment with NurOwn® ( $p\leq 0.050$ ) on this secondary endpoint.

(Emphasis added.)

***October 12, 2022 Press Release***

104. On October 12, 2022, after market hours, Brainstorm Cell issued a press release to announce the presentation of new biomarker analyses from its NurOwn Phase 3 ALS study. The press release continued to emphasize NurOwn's effectiveness, stating the following, in relevant part:

***“The new biomarker analyses presented today provide further evidence of NurOwn’s multifaceted mechanism of action and show consistent patterns in study participants regardless of the level of disease progression at baseline,”*** said Dr. Stacy Lindborg, Chief Development Officer at Brainstorm. “This compelling finding confirms the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints in our phase 3 trial and may further validate the results of subgroup analyses on clinical endpoints in our Phase 3 study which minimize the ALSFRS-R floor. When the subgroup of participants above 26 are analyzed, 2 points of function are preserved on average across 28 weeks in participants treated with NurOwn compared to placebo ( $p<.05$ ). Moreover, statistical modeling identified biomarkers that have the potential to predict clinical response to NurOwn observed in the trial, with markers of neuroinflammation, neurodegeneration, and neuroprotection selected in the final model. ***Novel therapies that simultaneously target multiple pathways may offer great potential in the treatment of ALS and highlights the advantages that may come with NurOwn’s ability to simultaneously modulate multiple biological pathways.***

\* \* \*



### Biomarker Data

- An analysis was performed to evaluate the effects of NurOwn and placebo on cerebrospinal fluid (CSF) biomarkers across pathways important to ALS of neuroinflammation, neurodegeneration and neuroprotection. Additional goals were to understand the role that baseline ALSFRS-R values plays on biomarker trajectories and to understand the predictive power of biomarkers on clinical outcomes.
- As observed in earlier trials, NurOwn was shown to decrease biomarkers associated with neuroinflammation and neurodegeneration, and increase neuroprotective biomarkers over 20 weeks, demonstrating its multifaceted mechanism of action.
- New analyses looked at the trajectory of biomarkers for the subgroups of participants with baseline ALSFRS-R scores  $>25$  and  $\leq 25$ , those most likely to be impacted by the floor effect of the scale. Decreases in neuroinflammatory and neurodegenerative markers and increases in neuroprotective markers in NurOwn treated participants compared to placebo were observed in both subgroups. ***These results indicate that NurOwn had similar biological effects on ALS participants regardless of the level of disease progression at baseline.***
- Further statistical modeling pre-specified prior to unblinding of the data identified three biomarkers that were predictive of clinical outcomes: baseline LAP, baseline neurofilament light (NfL) and mean change in Galectin-1. These biomarkers relate to neuroinflammatory, neurodegenerative, and neuroprotective pathways, respectively.

Chaim Lebovits, Chief Executive Officer of Brainstorm commented, ***“We are grateful to ALS ONE for the opportunity to present these important new data on NurOwn. The biomarker data and statistical analyses further our understanding of NurOwn’s mechanism of action and therapeutic potential.”***

(Emphasis added).

### ***November 10, 2022 Press Release***

105. On November 10, 2022, Brainstorm Cell issued a press release titled “BrainStorm Cell Therapeutics Receives Refusal to File Letter from FDA for its New Biologics License

Application for NurOwn for the treatment of ALS.” The press release stated the following, in relevant part:

“While we are disappointed that the FDA has not accepted our BLA for NurOwn in ALS, we remain committed to NurOwn's advancement as a treatment for this devastating disease. The company intends to request a Type A meeting and looks forward to continued discussions with the FDA,” said Chaim Lebovits, Chief Executive Officer of BrainStorm. “We continue to believe that NurOwn’s Phase 3 trial represents a significant contribution to ALS therapy and will continue to work tirelessly to address the needs of people living with ALS by advancing science and partnering with researchers around the world.”

The three, co-principal investigators of the NurOwn Phase 3 study were Dr. Robert Brown, Director of the Program in Neurotherapeutics at the University of Massachusetts Medical School, Dr. Merit Cudkowicz, Chief of Neurology at Massachusetts General Hospital, Julieanne Dorn Professor of Neurology at Harvard Medical School, Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital and Dr. Tony Windebank, Professor of Neurology and Judith and James Pape Adams Foundation Professor of Neuroscience at Mayo Clinic.

Drs. Brown, Cudkowicz and Windebank jointly stated, ***“While the pre-specified primary outcome measure was not met, there were participants with beneficial clinical effects and overall changes in relevant biomarkers of drug effect. Understanding whether there are people with ALS who might respond better to NurOwn is important given the unmet therapeutic need.*** As the three co-PIs of the Phase 3 study of NurOwn, we support continued discussions with the FDA on the best path forward.”

BrainStorm completed a Phase 3 trial in 200 participants with ALS (Cudkowicz et al., 2022 Muscle and Nerve). In the attempt to examine a real-world population, the study enrolled people with more advanced disease than other late-stage ALS trials. In fact, more than a third of these participants with advanced disease entered the trial with the one or more dimensions of physical function (e.g., dressing/hygiene, cutting food, walking) starting at the lowest possible score of 0 on the ALSFRS-R; thereby preventing the measurement of further deterioration. A pre-specified subgroup of participants, with baseline ALSFRS-R<sup>35</sup>, which controls for this “scale effect” showed a trend to a meaningful increase in the clinical response with NurOwn compared to placebo. The secondary endpoint, average ALSFRS-R change from baseline to 28 weeks in this subgroup, was statistically significant (p=0.050, Muscle and Nerve Supplemental File and Muscle and Nerve Erratum). In addition, post-hoc sensitivity analyses were presented last week (21st Annual NEALS Meeting 2022) which also showed a

statistical trend towards a clinically meaningful treatment effect with NurOwn across subgroups, and one that is consistent with the pre-specified subgroup of participants with less advanced ALS at baseline. ***Finally, biomarker data in all trial participants also showed consistent patterns of NurOwn reducing markers of inflammation and neurodegeneration, and increasing neuroprotective and anti-inflammatory markers relative to placebo, further supporting the notion that trial participants taking NurOwn are indeed experiencing a positive biological effect (ALS ONE Research Symposia 2022).***

(Emphasis added.)

106. On this news, the Company's share price fell \$1.22 per share, or 42.21%, from a closing price of \$2.89 per share on November 9, 2022 to close at \$1.67 per share on November 10, 2023.

***November 14, 2022 Press Release***

107. On November 14, 2022, before the market opened, Brainstorm Cell issued a press release on Form 8-K with the SEC wherein it announced its request for a Type A meeting with the FDA to "facilitate NurOwn's advancement following receipt of a refusal to file letter regarding the Company's new [BLA]." The press release downplayed the refusal to file letter and continued to tout NurOwn's effectiveness, stating the following, in relevant part:

"Our commitment to ALS patients and our belief in NurOwn's potential to address their unmet medical needs remains unchanged, despite our receipt of a refusal to file letter regarding our new Biologics License Application," said Chaim Lebovits, Chief Executive Officer of Brainstorm. "Our next step is to request a Type A meeting with the FDA, which will help us explore the best path forward to accomplish our goal of providing ALS patients with broad access to NurOwn. We believe that an important part of the regulatory process will be an FDA Advisory Committee meeting to discuss NurOwn, as this will allow a fair hearing in an open and transparent setting. We are grateful for the support we are receiving and look forward to providing more information on our Earnings Call around the FDA feedback we have received, and our next steps."

**Third Quarter 2022 and Recent Highlights**

- Additional analyses from NurOwn's Phase 3 ALS trial that account for measurement limitations in the lower part of the Revised ALS Functional Rating Scale (ALSFRS-R) were presented at the 21st Annual NEALS Meeting. *These analyses add to the robust body of evidence supporting a clinically meaningful treatment effect with NurOwn in ALS, as two complementary post-hoc sensitivity analysis methods showed that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn had a higher rate of clinical response and less function lost across 28 weeks compared to placebo.*
- Biomarker analyses from NurOwn's Phase 3 ALS trial presented at the 5th Annual ALS ONE Research Symposium confirmed the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints. The new biomarker data presented indicate that NurOwn had similar biological effects on Phase 3 trial participants regardless of the level of disease progression at baseline, providing further evidence confirming NurOwn's multifaceted mechanism of action. Furthermore, biomarkers spanning the 3 key pathways of neurodegeneration, neuroinflammation and neuroprotection were identified by a pre-specified model linking the changes in biomarkers in participants treated with NurOwn to the clinical outcomes observed in the trial. The presentation was delivered by Dr. Stacy Lindborg, Executive Vice President and Chief Development Officer at Brainstorm.
- Full results from a single-arm, Phase 2 trial of NurOwn were published in the peer-reviewed Multiple Sclerosis Journal. The results demonstrate NurOwn's safety and provide preliminary evidence of efficacy in patients with progressive multiple sclerosis (MS). *Treatment with NurOwn resulted in large, clinically meaningful improvements in some progressive MS patients, as defined by response criteria, across all endpoints measured.* These observed improvements diverged from what was seen in matched patients with progressive MS from the Comprehensive Longitudinal Investigation of Multiple Sclerosis (CLIMB) registry. In addition, biomarker analyses confirmed NurOwn's proposed mechanism of action in progressive MS by showing consistent treatment effects in neuroinflammation and neuroprotection pathways.
- Biomarker data from the Phase 2 trial of NurOwn in progressive MS was presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) by Jeffrey Cohen, MD, Hazel Prior Hostetler Endowed Chair and Professor of Neurology, Cleveland Clinic Lerner College of Medicine, Director, Experimental Therapeutics, Mellen Center for MS Treatment and Research. The presented data provide important biological context for the trial's observed clinical outcomes, as they showed NurOwn

treatment resulting in robust increases in neuroprotective biomarkers in cerebrospinal fluid.

(Emphasis added.)

***2022 Proxy Statement***

108. On December 13, 2022, Brainstorm Cell filed the 2022 Proxy Statement with the SEC. Defendants Almenoff, Arbel, Bairu, Frenkel, Polverino, Taub, and Yablonka solicited the 2022 Proxy Statement, filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.

109. The 2022 Proxy Statement called for shareholder approval of, *inter alia*: (1) the reelection of Defendants Almenoff, Arbel, Bairu, Frenkel, Polverino, Taub, and Yablonka to the Board; and (2) the ratification of the appointment of Brightman Almagor Zohar & Co., a firm in the Deloitte Global Network, as the independent registered public accounting firm of the Company for fiscal year 2023.

110. With respect to the Company's Risk Management and Oversight Process, the 2022 Proxy Statement stated the following:

The Board takes an active role, as a whole and at the committee level, in overseeing management of our Company's risks. Generally, the entire Board, the Audit Committee and the GNC Committee are involved in overseeing risks associated with the Company and monitor and assess those risks in reviews with management and with the Company's outside advisors and independent registered public accounting firm. The Audit Committee reviews regulatory risk, operational risk and enterprise risk, particularly as they relate to financial reporting, on a regular basis with management, the Company's independent registered public accounting firm and the Company's outside consultants and advisors. In its regular meetings, the Audit Committee discusses the scope and plan for the internal audit and includes management in its review of accounting and financial controls, assessment of business risks and legal and ethical compliance programs. The GNC Committee monitors the Company's governance and succession risk by review with management and outside advisors. The GNC Committee also monitors CEO succession and the

Company's compensation policies and related risks by reviews with management. The GNC Committee periodically reviews our compensation programs for employees to assure that these programs do not create risks that are reasonably likely to have a material adverse effect on the company.

111. Regarding the Code of Ethics, the 2022 Proxy Statement noted that the Audit Committee was responsible for "coordinating the Board's oversight of the Company's internal control over financial reporting, disclosure controls and procedures and code of conduct[.]"

112. The 2022 Proxy Statement was materially false and misleading because it failed to disclose that, contrary to the 2022 Proxy Statement's descriptions of the Board's risk oversight function and the Audit Committee's responsibilities, the Board and its committees were not adequately exercising these functions, were causing and/or permitting the Company to issue false and misleading statements, and were not complying with the Code of Ethics.

113. The 2022 Proxy Statement also failed to disclose, *inter alia*, that: (1) the Company downplayed the severity of the FDA's refusal to file letter; (2) the Company continued to conceal the risks associated with the submission of the BLA; and (3) as a result of the foregoing, Defendants' statements about Brainstorm Cell's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

114. As a result of Defendants Almenoff, Arbel, Bairu, Frenkel, Polverino, Taub, and Yablonka causing the 2022 Proxy Statement to be false and misleading, Company shareholders voted, *inter alia*, to re-elect each of them to the Board, thus allowing them to continue breaching their fiduciary duties to the Company.

***March 27, 2023 Press Release***

115. On March 27, 2023, before the market opened, Brainstorm Cell issued a press release wherein it announced the FDA Advisory Committee Meeting to review Brainstorm Cell's

BLA of NurOwn. Regarding the effectiveness of NurOwn, the press release stated the following, in relevant part:

Given the goal to proceed to an ADCOM as expeditiously as possible, BrainStorm requested that the Center for Biologics Evaluation and Research (CBER) utilize the FDA's File Over Protest procedure and has filed an amendment to the BLA which responds to most of the outstanding questions the FDA has posed.

“The FDA provided us with more than one path to an ADCOM for NurOwn. Our goal has always been to make NurOwn available to people living with ALS as quickly as possible, therefore we chose the File Over Protest pathway since this offered the fastest path to an ADCOM and regulatory decision relative to other pathways provided by the FDA,” said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. “The ALS community needs additional treatment options now, and we firmly believe our data support regulatory approval of NurOwn. We are grateful to the FDA for the opportunity to have the clinical evidence supporting NurOwn reviewed.”

Stacy Lindborg, Ph.D., BrainStorm's Co-Chief Executive Officer commented, “ALS is a horrific, neurodegenerative disease that moves at a terrifying speed, robbing people of their ability to move, speak, eat, and breathe. Securing an ADCOM represents an important step towards our goal of making NurOwn broadly available to individuals living with ALS who are in urgent need of new, effective therapies. The meeting will provide an open forum for BrainStorm and the FDA, together with medical experts, statisticians, and the ALS community, to thoughtfully review all available evidence supporting NurOwn. We remain confident in NurOwn and we are committed to doing everything in our power to make the product available quickly to people living with ALS. We look forward to a robust scientific discussion.”

116. On March 30, 2023, before the market opened, Brainstorm Cell issued a press release reminding investors about the upcoming FDA Advisory Committee Meeting. The press release continued to tout NurOwn's effectiveness, stating the following, in relevant part:

“Our priority in 2023 is to advance NurOwn® through the regulatory process as expeditiously as possible, including making preparations for our upcoming Advisory Committee Meeting,” said BrainStorm's President and Chief Executive Officer (CEO) Chaim Lebovits and Co-CEO Dr. Stacy Lindborg in a joint



statement. “The ADCOM will provide an invaluable opportunity for an open and thoughtful discussion among BrainStorm, regulators, ALS experts, and other key stakeholders on both the urgent need for new ALS therapies and the robust and intricate dataset that we believe supports NurOwn’s approval. As we move towards this important event, our clinical trial results and experienced team give us confidence in our ability to secure a successful outcome and execute on our mission of improving the lives of individuals with ALS.”

#### **Fourth Quarter 2022 and Recent Highlights**

U.S. Food and Drug Administration (FDA) notified BrainStorm in a written communication that the Agency will hold an Advisory Committee Meeting (ADCOM) to review the company’s Biologics License Application (BLA) for NurOwn for the treatment of amyotrophic lateral sclerosis (ALS).

- To meet its goal of proceeding to an ADCOM as expeditiously as possible, BrainStorm utilized the FDA’s File Over protest procedure to return the BLA to active review and filed an amendment which responds to most of the outstanding questions previously posed by the FDA. The Agency notified Brainstorm that it will set a date for the ADCOM as well as a Prescription Drug User Fee Act (PDUFA) target action date in due course.
- A presentation at the 2023 MDA Clinical and Scientific Conference delivered by Dr. Lindborg featured post hoc sensitivity analyses from NurOwn’s Phase 3 ALS trial. The presentation showed that a floor effect was observed in the PRO-ACT database, and a pattern of a plateau in ALSFRS-R total score was accompanied by scale items of 0 suggesting measurement challenges in those with advanced ALS due to the floor effect of the ALSFRS-R in the NurOwn phase 3 trial and historical studies which are included in the PRO-ACT database. Analyses conducted in participants not impacted by the floor effect at baseline of the NurOwn phase 3 trial revealed statistically significant, clinically meaningful effects with NurOwn on the primary and key secondary endpoints.
- Additional analyses from the Phase 3 trial of NurOwn in ALS were featured in a presentation at the 21st Annual NEALS Meeting. ***These analyses further strengthened the body of evidence supporting a clinically meaningful treatment effect with NurOwn in ALS.*** Two complementary post-hoc sensitivity analysis methods showed that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn had a higher rate of clinical response and less



function lost across 28 weeks compared to placebo. The presentation was codelivered by Dr. Lindborg and Merit Cudkowicz, MD, MSC, Chief of Neurology at Massachusetts General Hospital, Julieanne Dorn Professor of Neurology at Harvard Medical School, and Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital.

- Biomarker data from the Phase 3 trial of NurOwn in ALS were featured in a presentation delivered by Dr. Lindborg at the 5th Annual ALS ONE Research Symposium. The data showed NurOwn modulated pathways related to neurodegeneration, neuroinflammation, and neuroprotection, with changes that were consistent regardless of a participant's level of disease progression at baseline. These data provide further evidence of NurOwn's multifaceted mechanism of action and of the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints.
- Findings from the Phase 3 trial of NurOwn in ALS, including biomarker data and analyses accounting for the ALSFRS-R floor effect, were presented at the 13th Annual California ALS Research Summit by Dr. Lindborg. *The presentation demonstrated that NurOwn had significantly better outcomes in analyses controlling for the floor effect. Outcomes that aligned with historical data and power calculations of the trial.*
- Biomarker data from the Phase 2 trial of NurOwn in progressive multiple sclerosis were presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). The data showed robust increases in levels of neuroprotective biomarkers in cerebrospinal fluid with NurOwn treatment, thereby providing important biological context for clinical outcome data showing large, clinically meaningful improvements in some trial participants, as defined by response criteria, across all endpoints measured. These observed improvements diverged from what was seen in matched patients with progressive MS from the Comprehensive Longitudinal Investigation of Multiple Sclerosis (CLIMB) registry. The presentation was delivered by Jeffrey Cohen, MD, Hazel Prior Hostetler Endowed Chair and Professor of Neurology, Cleveland Clinic Lerner College of Medicine, Director, Experimental Therapeutics, Mellen Center for MS Treatment and Research.

(Emphasis added.)

117. On June 6, 2023, before the market opened, Brainstorm Cell issued a press release wherein it announced the FDA's plan to meet on September 27, 2023 to review the BLA for NurOwn. The press release continued to promote the effectiveness of NurOwn, stating the following, in relevant part:

"We are encouraged by the regulatory flexibility that the FDA has shown over the last year in ALS broadly, and with respect to NurOwn in particular, and believe an Advisory Committee meeting is good for patients," said Chaim Lebovits, BrainStorm President & CEO. "We are of course deeply committed to the scientific and regulatory process, which includes continuing research to confirm the results of the NurOwn clinical program and are working with ALS experts in designing a rigorous clinical study to answer important questions about this therapy and inform further research on ALS."

Stacy Lindborg, Ph.D., BrainStorm co-CEO, commented: ***"We welcome the opportunity to present our data at the forthcoming ADCOM. We remain confident in NurOwn and believe our data support regulatory approval.*** As is the case with most ALS research, our clinical program generated complex results, which deserve a thoughtful and holistic review by scientists, ALS experts, FDA reviewers, advocates, and patients. We believe this approach honors the needs of those living with ALS and offers the greatest promise for BrainStorm to fulfill our commitment to the ALS community."

(Emphasis added).

118. On August 14, 2023, before the market opened, Brainstorm Cell issued a press release wherein it restated its preparations for its meeting with the FDA on September 27, 2023 to review the BLA for NurOwn. The press release continued to tout the effectiveness of NurOwn, stating the following, in relevant part:

BrainStorm's immediate priorities are to prepare for the upcoming ADCOM meeting to review the BLA for NurOwn®, scheduled for September 27, and complete preparations for commercial launch. The Company's senior team is working with expert consultants to ensure it will deliver a compelling presentation to the ADCOM and is prepared to address the questions that the FDA and members of the committee might raise.

“We appreciate the FDA's guidance and input throughout the review process, which will be instrumental in making a policy decision that meets the needs of those living with ALS,” said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. “In parallel with the regulatory work, we are preparing the company for success, with the goal of making NurOwn available to patients, if approved in December.”

Dr. Stacy Lindborg, Co-Chief Executive Officer of BrainStorm commented, “We look forward to discussing NurOwn's full dataset at the forthcoming ADCOM meeting. Our clinical program has generated complex results, and the ADCOM meeting will provide us with the opportunity for a thoughtful discussion with scientists, ALS experts, FDA reviewers, advocates, and patients. We have full confidence in the data we have compiled, and believe that a comprehensive analysis of our results strongly supports NurOwn's clinically meaningful effectiveness. In addition, we continue to share our data with the ALS community at scientific meetings and recently delivered an important presentation at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference. The data from this new analysis showed that treatment with NurOwn significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including neurofilament light (NfL). Reductions in plasma NfL are believed to be a predictor of clinical benefit in ALS.”

## **Second Quarter 2023 and Recent Highlights**

### Clinical and regulatory.

- The U.S. Food and Drug Administration (FDA) notified BrainStorm that a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee to review the BLA for NurOwn® has been scheduled for September 27, 2023. In addition, BrainStorm's BLA for NurOwn has been assigned a PDUFA action date targeted to occur by December 8, 2023.
- In July 2023, new biomarker data from the Phase 3 trial of NurOwn were presented at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference. These data show that treatment with NurOwn significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including NfL over time compared to placebo in all trial participants. It is believed that reductions in plasma NfL are reasonably likely to predict clinical benefit in ALS.

(Emphasis added.)

119. The statements identified in ¶¶ 103-105, 107, and 115-118 above were materially false and/or misleading and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, the identified statements failed to disclose that: (1) the Company downplayed the severity of the FDA's refusal to file letter; (2) the Company continued to conceal the risks associated with the submission of the BLA; and (3) as a result of the foregoing, Defendants' statements about Brainstorm Cell's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

### **The Truth Emerges**

120. On September 27, 2023, Brainstorm Cell announced the results of the FDA's review of its BLA in a press release. Notably, the Company revealed that members of the Cellular, Tissue, and Gene Therapies Advisory Committee voted 17 to 1 that there was not substantial evidence to show NurOwn's effectiveness. The press release stated the following, in relevant part:

Today the Committee voted that NurOwn did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS.

“The Committee's vote was a sad outcome for the ALS community, who have too few options to help manage this merciless and deadly disease,” said Stacy Lindborg, PhD, co-CEO of BrainStorm. “We firmly believe that the totality of data presented for NurOwn today provide a compelling case for approval, with clinical evidence in those with less advanced disease supported by strong and consistent biomarker data that are predictive of clinical response. We truly did our best to make the NurOwn data clear to the FDA Advisory Committee. Unfortunately, had more time and opportunity been allowed, many remaining questions posed by Advisory Committee members could have been sufficiently addressed.”

121. The FDA briefing document revealed that the Company had significantly downplayed the risks associated with NurOwn, noting that there was not enough evidence to support NurOwn's effectiveness and that there were large amounts of missing data in the Company's BLA. The document stated the following, in relevant part:

On initial receipt of the BLA, *FDA determined that the submission was scientifically incomplete to demonstrate substantial evidence of effectiveness, and that the manufacturing information was grossly deficient to ensure adequate product quality.* Examples of critical information not provided in the BLA submission include missing or inadequate control of materials, validation of methods missing or incomplete, lack of data demonstrating manufacturing consistency, control strategy for prefilled syringe not provided, inadequate manufacturing and testing facility information, and facilities not ready for inspection.

FDA therefore refused to file the submission and detailed these deficiencies in a Refuse to File (RTF) letter to the Applicant. The Applicant elected to request that the BLA to be filed over protest, and subsequently provided further retrospective analyses and biomarker results.

\* \* \*

(2) Survival in the Phase 3 study was worse at study completion for subjects who received MSC-NTF. A total of 13 deaths occurred during the post-treatment follow up (28 weeks  $\pm$  5 days) with 10 deaths (10/95) in the MSC-NTF group and 3 deaths (3/94) in the placebo group. The Kaplan-Meier (KM) estimate of survival at Week 28 ( $\pm$  5 days) was 88.3% (95% CI: 79.3, 93.6) for the MSC-NTF group and 94.4% (95% CI: 81.2, 98.4) for the placebo group, with a nominal pvalue of 0.04 from unadjusted log rank test.

***This outcome suggests the lack of efficacy of MSC-NTF on survival of patients with ALS.***

(3) The Applicant performed three different retrospective analyses on an unblinded, post-hoc subgroup from the Phase 3 study, excluding in each certain subjects based on the assertion of a “floor effect” in the ALSFRS-R, according to different criteria. A floor effect refers to insensitivity of an outcome measure to differences at the lower end of an assessment scale. In this case, the Applicant claims that a floor effect results in plateauing of ALSFRS-R total scores over time, during which further deterioration of function cannot be measured. ***However, no floor effect was demonstrated in the analyses. In addition, floor effect would not be expected in the assessment of survival or biomarkers. Of note, when assessed by change in ALSFRS-R total score from baseline to Week 28, the MSCNTF subjects ostensibly affected by a “floor effect” in fact experienced a numerically larger decline in function over time than did the corresponding placebo subjects. This result indicates continued deterioration of function and suggests lack of treatment benefit for MSC-NTF subjects.***

(4) In the Phase 3 study, the Applicant collected cerebrospinal fluid (CSF) samples at baseline, Weeks 2, 4, 8, 12, 16, and 20 post-Treatment 1, and examined levels of multiple biomarkers. The Applicant then conducted numerous exploratory analyses, including multiple post hoc analyses, to evaluate the relationships between the selected biomarkers and clinical efficacy outcomes, to support the claim of effectiveness. Of note, there was a large amount of missing data for all biomarkers at Week 20 (~50%), the last time point for biomarker sample collection and the focused time point for biomarker analyses.

\* \* \*

***The Applicant submitted the BLA on September 9, 2022. FDA conducted a filing review and determined that a substantive review could not be performed, because the BLA submission was scientifically incomplete and grossly deficient. Critical clinical and manufacturing deficiencies were identified. For clinical, the completed randomized, placebo-controlled clinical studies failed to show efficacy in their prospectively specified efficacy endpoints to demonstrate required substantial evidence of effectiveness. For manufacturing, the required Chemistry, Manufacturing, and Controls information covering several critical categories was not included in the application, and the level of information included was insufficient to perform a full assessment of product quality. Consequently, FDA issued a refuse-to-file letter to the Applicant on November 8, 2022.***

\* \* \*

***FDA has concerns about the consistency of the manufacturing process and potential sources of product variability. It is important for licensure the Applicant demonstrate the manufacturing process is under a state of control.*** Chemistry, Manufacturing, and Control regulations are intended to assure that all subjects receive a quality product lot, including for safety and potency. Data supporting a product can come from in-process and final product properties, and from clinical data of safety and efficacy. ***However, for this BLA clinical data supporting safety for all patients is unclear, and efficacy has not been demonstrated.***

\* \* \*

In addition to concerns about the adequacy of the existing manufacturing control strategy, there are concerns about manufacturing changes – either those that occurred during clinical development under IND, or for the proposed commercial product.

\* \* \*

The primary efficacy endpoint and all key secondary endpoints failed to demonstrate efficacy of MSC-NTF compared to placebo (see Appendix III).

From the statistical perspective, when the primary efficacy endpoint in a clinical study fails to show statistical significance, the secondary efficacy endpoints cannot be tested with Type I error control. In accordance with the Agency's discussions with the Applicant (Face-to-Face Meeting, November 18, 2019), however, FDA reviewed all primary and key secondary endpoint results. The Agency did so for several reasons: (1) although at that meeting the Applicant expressed openness to changing the primary efficacy endpoint from a slope-based analysis, FDA recommended against doing so, in order to avoid compromising the integrity of the Phase 3 study, which the Applicant had already initiated; (2) data for the outcome measures recommended by the Agency, such as CAFS or survival, were collected by the Applicant as secondary efficacy endpoints; and (3) FDA's willingness to exercise regulatory flexibility and desire to better inform subjects and stakeholders.

#### Primary Efficacy Endpoint

***For the Applicant's primary efficacy endpoint, the percent of responders in the MSC-NTF group versus the placebo group did not show a statistically significant difference:*** the MSC-NTF group had 32.6% (31/95) responders and the placebo group had 27.7% (26/94). The odds ratio after adjusting for the predefined covariates was 1.33 (95% CI: 0.63, 2.80) with a p-value of 0.45.

#### Key Secondary Efficacy Endpoints

***All key secondary efficacy endpoints failed to show efficacy of MSC-NTF.*** For example, the least squares (LS) mean CAFS scores at Week 28 did not differ significantly between subjects in the MSC-NTF group and those in the placebo group (3.0: 96.5 versus 93.5; 95% CI: -11.4, 17.4; nominal p-value: 0.68). Similarly, there was minimal difference in LS mean change from baseline to Week 28 in ALSFRS-R total score (0.4: -5.5 versus -5.9; 95% CI: -1.47, 2.20; nominal p-value: 0.69).

\* \* \*

In addition to this analysis, at the Type A meeting with the FDA after refusal to file of the BLA, the Applicant presented a third post-hoc floor effect analysis in which the no floor effect subgroup was defined as ALSFRS-R Item Level had no value 0 at baseline (Definition 3).

We will refer to these subgroups identified by the Applicant collectively as "no floor effect subgroup" and their respective complement "floor effect subgroup." In



the “no floor effect subgroup” identified by different definitions, some of the clinical endpoints showed “statistical significance” per the Applicant (Appendix IV); however, ***FDA believes these findings from the exploratory subgroup analysis can only be used for hypothesis generation, not as evidence of effectiveness to support approval, for the following reasons:***

(1) Post-hoc subgroup analyses in general have high risk of finding false positive results due to lack of control for multiple hypothesis testing and potential confounding due to imbalance in the measured/unmeasured baseline prognostic factors brought about by breaking the randomization. What is particularly concerning in this case is that there is no solid definition for the “no floor effect subgroup” (i.e., subgroup of trial subjects not impacted by floor effect). The “no floor effect subgroup” can potentially be defined in many ways, as illustrated by the three distinct subgroups identified by the Applicant, with various sample sizes (145, 159, and 106 subjects respectively). As one could define “no floor effect subgroup” in many ways, some of the “no floor effect subgroup” (like the three selected by the Applicant) may happen to show “positive” findings (i.e., findings that seem to suggest clinical efficacy) among many other subgroups that may show “negative” findings (i.e., findings that seem to suggest harm). These findings could be due to random chance, given the potentially large number of subgroups the Applicant could examine. Therefore, these findings need to be confirmed by additional adequate and well-controlled clinical study(ies) to establish their validity; these findings cannot be used as evidence of effectiveness to meet the statutory standard for this BLA.

(2) MSC-NTF appeared to have a detrimental effect in the floor effect subgroups (Appendix IV). For example, the placebo group had a better CAFS ranking than the MSC-NTF group with a nominal p-value of 0.026 in the floor effect subgroup defined by ALSFRS-R Total Score baseline  $\leq 25$  (Definition 1). The floor effect subgroups defined by the other two methods had the same issue. This is not surprising; given that the overall treatment effect was close to zero, when one subgroup happens to show a strong positive treatment effect, the complementary subgroup is highly likely to have a strong negative effect. The “negative” findings in the floor effect subgroup thus may well be false “negative,” in the same way that the “positive” findings in the no floor effect subgroup may well be false positives.

(3) FDA did not observe a “floor effect” in the floor effect subgroup defined by any of the three definitions identified by the Applicant. If there were a “floor effect” in the Applicant-identified floor effect subgroup, the ALSFRS-R total score post baseline would have been bounded by a “floor,” which would have prevented the score from much further decline. This is in



direct contrast with the fact that the MSC-NTF “floor effect subgroup” had a drastically steeper decline in ALSFRS-R total score from baseline compared with the no floor effect subgroup or the placebo floor effect subgroup. At the same time, the magnitude of change between the placebo floor effect subgroup and the placebo no floor effect subgroup were comparable, which further puts into question the validity of the “floor effect” (Figure 12 [using Definition 1] and Figure 14 [using Definition 3]). In addition, the MSC-NTF floor effect subgroup showed substantially worse CAFS ranking than the no floor effect subgroups while the two placebo subgroups were comparable Figure 13. In conclusion, the lack of efficacy of MSC-NTF over placebo cannot be explained by a floor effect.

\* \* \*

The Applicant conducted exploratory subgroup analysis of “rapid progressors” versus “slow progressors.” The Applicant defined “rapid progressors” as subjects with  $\geq 2$  points decline from screening to baseline (~3 months) in the ALSFRS-R total score; correspondingly, “slow progressors” were defined as subjects with  $< 2$  points decline from screening to baseline in ALSFRS-R total score. As FDA stated in the November 18, 2019, Type C Meeting Summary:

***“We interpret your Phase 2 data as evidence that your product is not effective in the treatment of ALS. Your proposal that your Phase 2 data suggest benefit for the ‘rapid progressors’ is most likely overinterpretation of your subgroup analyses.*** In subgroup analyses, the results for the ‘slow progressors’ could be interpreted to suggest that your product is harmful to some patients with ALS. However, such subgroup results, for both the ‘rapid progressors’ and the ‘slow progressors’, are most likely spurious and misleading, as is often the case for such subgroup analyses. We note that it is not clear why a product that you propose to have neuroprotective and immunomodulatory effects would be beneficial for some patients with ALS and harmful to other patients with ALS. Due to their inconsistency (i.e., opposite effects in ‘rapid progressors’ versus ‘slow progressors’), and the unclear biological plausibility for such inconsistency, your subgroup results do not support that your product has any meaningful activity in the treatment of ALS” [].

Despite FDA’s consistent concern about the definition of “rapid progressors,” and the exploratory nature of the subgroup findings, the Applicant decided to enroll only “rapid progressors” in the Phase 3 study. For that study, the Applicant modified the definition of a “rapid progressor” to be subjects who experienced at least a 1.0-point decline in ALSFRS-R per month, on average, during the 3-month pretreatment period.

\* \* \*

***In Study BCT-002-US, the biomarker analyses were limited by the large amount of missing data. Biomarker data were only collected up to Week 20, but the efficacy data were collected up to Week 28. At Week 20, the key biomarkers that the Applicant identified, NfL, galectin-1, MCP-1, VEGF-A, and LAP, had up to approximately 50% missing data.*** In general, this degree of missing data compromises the validity of the analyses and could lead to over-estimation of the correlations between the biomarkers and efficacy endpoints. This missing data problem was further exacerbated when those post-hoc subgroup analyses were conducted based on different “floor effect” hypothesis.

Although the Applicant added the biomarker addendum to the statistical analysis plan before the data were unblinded, numerous biomarker analyses were proposed without multiplicity adjustment or formal hypothesis testing. The results from those biomarker analyses can only be considered as exploratory because there was no overall Type I error rate control, and any nominal “statistical significance” claim (nominal  $p \leq 0.05$ ) could be due to chance alone.

Additionally, the applicant conducted multiple post-hoc analyses after the data were unblinded. These post-hoc analyses could be biased as the data are unblinded and analyses can be made to produce a more favorable result. Thus, post-hoc analyses in general have a high chance of false positive findings.

***In summary, FDA does not believe there is sufficient evidence to support that any of the assessed biomarkers is reasonably likely to predict clinical benefit. Considering the potential mechanism of action of MSC-NTF, which may involve multiple pathways, it is challenging to use biomarker data to support effectiveness of MSC-NTF based on exploratory analyses of multiple biomarkers. There were also large amounts of missing data.*** In the case of NfL, which is released into the CSF by damaged or degenerating axons, higher reduction from baseline at Week 20 of CSF NfL levels were seen in subjects with poorer efficacy outcome (measured by ALSFRS-R score changes from baseline at Week 28), the opposite of what would be expected. These findings could be due to 50% of missing NfL data at Week 20 and relatively overall small changes in NfL in MSC-NTF group. Either way in the setting of negative phase 3 study results, the findings related to NfL do not appear to provide direct evidence on treatment effect through changes in NfL.

\* \* \*

## 6.2 Safety Summary

- (1) The higher incidence of deaths in the MSC-NTF group which indicates lack of survival benefit of MSC-NTF and warrants further investigation.
- (2) There appears to be a higher incidence of respiratory failure and dysphagia in the MSC-NTF group.
- (3) There appears to be a higher incidence of pain (e.g., coccydynia and back pain) in the MSC-NTF group.

(Emphasis added)

122. Also on September 27, 2023, *Reuters* published an article titled “US FDA panel votes against BrainStorm's ALS therapy over effectiveness concern,” wherein it summarized the FDA’s decision and stated the following, in relevant part:

***The U.S. Food and Drug Administration's (FDA) staff reviewers said on Monday there is not enough evidence to support NurOwn's effectiveness and that there are large amounts of missing data in the company's application.***

"Providing false hope can be ethically problematic and false hope is provided when the probability of a positive outcome is overestimated. And I think that seems to be the case here," said Lisa Lee, one of the panelists.

(Emphasis added.)

123. On this news, Brainstorm Cell’s share price fell \$0.19 per share, or 48.72%, from a closing price of \$0.39 per share on September 27, 2023 to close at \$0.20 per share on September 28, 2023.

## **DAMAGES TO BRAINSTORM CELL**

146. As a direct and proximate result of the Individual Defendants’ conduct, Brainstorm Cell has lost and expended, and will continue to lose and expend, many millions of dollars.

147. Such expenditures include, but are not limited to, legal fees, costs, and any payments for resolution of or to satisfy a judgment associated with the Securities Class Action, and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

148. Such expenditures also include, but are not limited to, fees, costs, and any payments for resolution of or to satisfy judgments associated with any other lawsuits filed against the Company or the Individual Defendants based on the misconduct alleged herein, and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

149. Such expenditures will also include costs incurred in any internal investigations pertaining to violations of law, costs incurred in defending any investigations or legal actions taken against the Company due to its violations of law, and payments of any fines or settlement amounts associated with the Company's violations.

150. Additionally, these expenditures include, but are not limited to, unjust compensation, benefits, and other payments provided to the Individual Defendants who breached their fiduciary duties to the Company.

151. As a direct and proximate result of the Individual Defendants' conduct, Brainstorm Cell has also suffered and will continue to suffer a loss of reputation and goodwill, and a "liar's discount" that will plague the Company's stock in the future due to the Company's and their misrepresentations.

### **DERIVATIVE ALLEGATIONS**

152. Plaintiff brings this action derivatively and for the benefit of Brainstorm Cell to redress injuries suffered, and to be suffered, as a result of the Individual Defendants' breaches of their fiduciary duties as directors and/or officers of Brainstorm Cell, unjust enrichment, abuse of

control, gross mismanagement, waste of corporate assets, violations of the Exchange Act, the aiding and abetting thereof, as well as for contribution under Sections 10(b) and 21D of the Exchange Act.

153. Brainstorm Cell is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

154. Plaintiff is, and has been at all relevant times, a shareholder of Brainstorm Cell. Plaintiff will adequately and fairly represent the interests of Brainstorm Cell in enforcing and prosecuting its rights, and, to that end, have retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

#### **DEMAND FUTILITY ALLEGATIONS**

155. Plaintiff incorporates by reference and realleges each and every allegation stated above as if fully set forth herein.

156. A pre-suit demand on the Board of Brainstorm Cell is futile and, therefore, excused. At the time of filing of this action, the Board consists of the following seven individuals: Defendants Arbel, Bairu, Frenkel, Polverino, Yablonka, Almenoff, and Naor (the “Director Defendants”). Plaintiff needs only to allege demand futility as to four of the seven Director Defendants who are on the Board at the time this action is commenced.

157. Demand is excused as to all of the Director Defendants because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of the scheme they engaged in knowingly or recklessly to make and/or cause the Company to make false and misleading statements and omissions of material facts. This renders the Director Defendants

unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

158. Moreover, each of the Director Defendants other than Defendant Naor solicited the 2022 Proxy Statement to call for a shareholder vote to, *inter alia*, re-elect themselves to the Board, thus allowing them to continue breaching their fiduciary duties to the Company.

159. In complete abdication of their fiduciary duties, the Director Defendants either knowingly or recklessly caused or permitted Brainstorm Cell to issue materially false and misleading statements. Specifically, the Director Defendants caused the Company to issue false and misleading statements which were intended to make the Company appear more profitable and attractive to investors. Moreover, the Director Defendants caused the Company to fail to maintain internal controls. As a result of the foregoing, the Director Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

160. Additional reasons that demand as to Defendant Arbel is futile follow. Defendant Arbel co-founded the Company and has served as a Company director since May 2004. She also serves as the Vice-Chairperson of the Board, as the Chair of the Governance, Nominating and Compensation Committee, and as a member of the Audit Committee. As the Company's trusted Vice-Chairperson, she conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded her duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded her duties to protect corporate assets. As a result, Defendant Arbel breached her fiduciary duties, faces a

substantial likelihood of liability, and is not independent or disinterested. Thus, demand upon Defendant Arbel is futile and excused.

161. Additional reasons that demand as to Defendant Bairu is futile follow. Defendant Bairu has served as Company director since October 2021. Defendant Bairu has received and continues to receive compensation for his role as a director as described above. As a trusted Company director, Defendant Bairu conducted little, if any, oversight of the scheme to cause Brainstorm Cell to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. As a result, Defendant Bairu breached his fiduciary duties, faces a substantial likelihood of liability, and is not independent or disinterested. Thus, demand upon Defendant Bairu is futile and excused.

162. Additional reasons that demand as to Defendant Frenkel is futile follow. Defendant Frenkel has served as a Company director and Chairperson since March 2020. He has received and continues to receive compensation for his role as a director as described above. As a trusted Company director, Defendant Frenkel conducted little, if any, oversight of the scheme to cause Brainstorm Cell to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. As a result, Defendant Frenkel breached his fiduciary duties, faces a substantial likelihood of liability, and is not independent or disinterested. Thus, demand upon Defendant Frenkel is futile and excused.

163. Additional reasons that demand as to Defendant Polverino is futile follow. Defendant Polverino has served as Company director since February 2018. He also serves as a

member of the Governance, Nominating and Compensation Committee. In addition, he has received and continues to receive compensation for his role as a director as described above. As a trusted Company director, Defendant Polverino conducted little, if any, oversight of the scheme to cause Brainstorm Cell to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. As a result, Defendant Polverino breached his fiduciary duties, faces a substantial likelihood of liability, and is not independent or disinterested. Thus, demand upon Defendant Polverino is futile and excused.

164. Additional reasons that demand as to Defendant Yablonka is futile follow. Defendant Yablonka has served as a Company director since June 2014 and as the Company's Executive Vice President, Chief Business Officer since March 6, 2017. As a trusted Company director, Defendant Yablonka conducted little, if any, oversight of the scheme to cause Brainstorm Cell to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. As a result, Defendant Yablonka breached his fiduciary duties, faces a substantial likelihood of liability, and is not independent or disinterested. Thus, demand upon Defendant Yablonka is futile and excused.

165. Additional reasons that demand as to Defendant Naor is futile follow. Defendant Naor has served as Company director since June 2023. He also serves as Chair of the Audit Committee and as a member of the Governance, Nominating and Compensation Committee. As a trusted Company director, Defendant Naor conducted little, if any, oversight of the scheme to cause Brainstorm Cell to make false and misleading statements, consciously disregarded his duties



to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. As a result, Defendant Naor breached his fiduciary duties, faces a substantial likelihood of liability, and is not independent or disinterested. Thus, demand upon Defendant Naor is futile and excused.

166. Additional reasons that demand as to Defendant Almenoff is futile follow. Defendant Almenoff has served as a Company director since February 26, 2017. Defendant Almenoff also served on the Audit Committee until December 2023. In addition, she has received and continues to receive compensation for her role as a director as described above. As a trusted Company director, she conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded her duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded her duties to protect corporate assets. As a result, Defendant Almenoff breached her fiduciary duties, faces a substantial likelihood of liability, and is not independent or disinterested. Thus, demand upon Defendant Almenoff is futile and excused.

167. Additional reasons that demand on the Board is futile follow.

168. Defendant Arbel, Naor, and Almenoff (the “Audit Committee Defendants”) served as a member of the Company’s Audit Committee during the Relevant Period. They violated the Audit Committee Charter by failing to adequately exercise their risk management and risk assessment functions and failing to ensure adequate Board oversight of the Company’s internal control over financial reporting, disclosure controls and procedures, and Code of Ethics. Thus, the Audit Committee Defendants breached their fiduciary duties and are not disinterested. Therefore, demand is further excused and futile as to them.

169. In violation of the Code of Ethics, the Director Defendants engaged in or permitted the scheme to cause the Company to issue materially false and misleading statements to the investing public, and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violations of the Exchange Act. In addition, the Individual Defendants violated the Code of Ethics by failing to act with integrity, failing to avoid conflicts of interest, failing to ensure the Company's disclosures were accurate, failing to ensure the Company complied with applicable laws, rules, and regulations, and failing to promptly report known violations of the Code of Ethics and the law. Thus, the Director Defendants breached the Company's own Code of Ethics, are not disinterested, and demand is excused as to them.

170. Brainstorm Cell has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Director Defendants have not filed any lawsuits against themselves or any others who were responsible for the wrongful conduct to attempt to recover for Brainstorm Cell any part of the damages Brainstorm Cell suffered and will continue to suffer thereby. Thus, any demand upon the Director Defendants would be futile.

171. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Director Defendants can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Director Defendants face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable

of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

172. The acts complained of herein constitute violations of fiduciary duties owed by Brainstorm Cell's officers and directors, and these acts are incapable of ratification.

173. The Director Defendants may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Brainstorm Cell. If there is a directors' and officers' liability insurance policy covering the Director Defendants, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Director Defendants, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Director Defendants were to sue themselves or certain of the officers of Brainstorm Cell, there would be no directors' and officers' insurance protection. Accordingly, the Director Defendants cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Director Defendants is futile and, therefore, excused.

174. If there is no directors' and officers' liability insurance, then the Director Defendants will not cause Brainstorm Cell to sue the Individual Defendants named herein, since, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

175. Thus, for all of the reasons set forth above, all of the Director Defendants, and, if not all of them, at least four of them, cannot consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

### **FIRST CLAIM**

#### **Against the Individual Defendants for Violations of Section 14(a) of the Exchange Act**

146. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

147. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that “[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l].”

148. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. § 240.14a-9.

149. Under the direction and watch of Defendants Almenoff, Arbel, Bairu, Frenkel, Polverino, Taub, and Yablonka, the 2022 Proxy Statement failed to disclose that, contrary to the 2022 Proxy Statement’s descriptions of the Board’s risk oversight function and the Audit

Committee's responsibilities, the Board and its committees were not adequately exercising these functions, were causing and/or permitting the Company to issue false and misleading statements, and were not complying with the Code of Ethics.

150. The 2022 Proxy Statement also failed to disclose that: (1) the Company downplayed the severity of the FDA's refusal to file letter; (2) the Company continued to conceal the risks associated with the submission of the BLA; and (3) as a result of the foregoing, Defendants' statements about Brainstorm Cell's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

151. In the exercise of reasonable care, the Individual Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2022 Proxy Statement were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the 2022 Proxy Statement, including but not limited to, the election of Defendants Arbel, Almenoff, Frenkel, Polverino, Taub, Yablonka, and Bairu to the Board.

152. The false and misleading elements of the 2022 Proxy Statement led to, among other things, the election of Defendants Arbel, Almenoff, Frenkel, Polverino, Taub, Yablonka, and Bairu, which allowed them to continue to breach their fiduciary duties to Brainstorm Cell.

153. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions in the 2022 Proxy Statement.

154. Plaintiff, on behalf of Brainstorm Cell, has no adequate remedy at law.

## **SECOND CLAIM**

### **Against the Individual Defendants for Breach of Fiduciary Duties**

155. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

156. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Brainstorm Cell's business and affairs.

157. Each of the Individual Defendants violated and breached his or her fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

158. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Brainstorm Cell.

159. In breach of their fiduciary duties owed to Brainstorm Cell, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and/or misleading statements and/or omissions of material fact that failed to disclose, *inter alia*, that: (1) the Company downplayed the severity of the FDA's refusal to file letter; (2) the Company continued to conceal the risks associated with the submission of the BLA; and (3) as a result of the foregoing, Defendants' statements about Brainstorm Cell's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

160. The Individual Defendants failed to correct and/or caused the Company to fail to correct the false and misleading statements and omissions of material fact, thus rendering them personally liable to the Company for breaching their fiduciary duties.

161. Also in breach of their fiduciary duties, the Individual Defendants caused the Company to fail to maintain internal controls.

162. The Individual Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were available to them.

163. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent scheme set forth herein and to fail to maintain adequate internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent scheme and to fail to maintain adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Brainstorm Cell's securities. The Individual Defendants, in good faith, should have taken appropriate action to correct the scheme alleged herein and to prevent it from continuing to occur.

164. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

165. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Brainstorm Cell has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

166. Plaintiff, on behalf of Brainstorm Cell, has no adequate remedy at law.

### **THIRD CLAIM**

#### **Against the Individual Defendants for Unjust Enrichment**

167. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

168. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Brainstorm Cell.

169. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Brainstorm Cell that was tied to the performance or artificially inflated valuation of Brainstorm Cell, or received compensation or other payments that were unjust in light of the Individual Defendants' bad faith conduct.

170. Plaintiff, as a shareholder and representative of Brainstorm Cell, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, including from insider transactions, the redemption of preferred stock, benefits, and other compensation, including any performance-based or valuation-based compensation, obtained by the Individual Defendants due to their wrongful conduct and breaches of their fiduciary and contractual duties.

171. Plaintiff, on behalf of Brainstorm Cell, has no adequate remedy at law.

### **FOURTH CLAIM**

#### **Against the Individual Defendants for Abuse of Control**

172. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.



173. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Brainstorm Cell, for which they are legally responsible.

174. As a direct and proximate result of the Individual Defendants' abuse of control, Brainstorm Cell has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

175. Plaintiff, on behalf of Brainstorm Cell, has no adequate remedy at law.

#### **FIFTH CLAIM**

##### **Against the Individual Defendants for Gross Mismanagement**

176. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

177. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Brainstorm Cell in a manner consistent with the operations of a publicly-held corporation.

178. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Brainstorm Cell has sustained and will continue to sustain significant damages.

179. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

180. Plaintiff, on behalf of Brainstorm Cell, has no adequate remedy at law.

#### **SIXTH CLAIM**

##### **Against the Individual Defendants for Waste of Corporate Assets**

181. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

182. As a further result of the foregoing, the Company will incur many millions of dollars of legal liability and/or costs to defend unlawful actions (as evidenced, for example, by the Securities Class Action), to engage in internal investigations, and to lose financing from investors and business from future customers who no longer trust the Company and its products.

183. As a result of the waste of corporate assets, the Individual Defendants are each liable to the Company.

184. Plaintiff, on behalf of Brainstorm Cell, has no adequate remedy at law.

#### **SEVENTH CLAIM**

#### **Against Defendants Lebovits and Lindborg for Contribution Under Sections 10(b) and 21D of the Exchange Act**

185. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

186. Brainstorm Cell and Defendants Lebovits and Lindborg are named as defendants in the Securities Class Action, which asserts claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Action for these violations of the federal securities laws, the Company's liability will be in whole or in part due to Defendant Lebovits's and Defendant Lindborg's willful and/or reckless violations of their obligations as officers and/or directors of the Company.

187. Defendants Lebovits and Lindborg, because of their positions of control and authority as officers and/or directors of the Company, were able to and did, directly and/or

indirectly, exercise control over the business and corporate affairs of the Company, including the wrongful acts complained of herein and in the Securities Class Action.

188. Accordingly, Defendants Lebovits and Lindborg are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

189. As such, Brainstorm Cell is entitled to receive all appropriate contribution or indemnification from Defendants Lebovits and Lindborg.

### **PRAYER FOR RELIEF**

FOR THESE REASONS, Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows:

(a) Declaring that Plaintiff may maintain this action on behalf of Brainstorm Cell, and that Plaintiff is an adequate representative of the Company;

(b) Declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Brainstorm Cell;

(c) Determining and awarding to Brainstorm Cell the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

(d) Directing Brainstorm Cell's and the Individual Defendants to take all necessary actions to reform and improve Brainstorm Cell's corporate governance and internal procedures to comply with applicable laws and to protect Brainstorm Cell and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting

forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Certificate of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies:

1. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the board;

2. a provision to permit the shareholders of Brainstorm Cell to nominate at least four candidates for election to the Board;

3. a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations;

(e) Awarding Brainstorm Cell restitution from Individual Defendants, and each of them;

(f) Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

(g) Granting such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Dated: March 21, 2024

**THE BROWN LAW FIRM, P.C.**

/s/ Timothy Brown  
Timothy Brown  
Saadia Hashmi

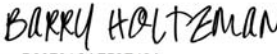
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*Counsel for Plaintiff*

**VERIFICATION**

I, Barry Holtzman, am a plaintiff in the within action. I have reviewed the allegations made in this Shareholder Derivative Complaint, know the contents thereof, and authorize its filing. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 20 day of March, 2024.

DocuSigned by:  
  
B69731CAF50E43A...  
Barry Holtzman